Lay Language Summary

PHERGain MRI vs PET

Comparing 18F-FDG positron emission tomography (PET) and breast magnetic resonance imaging (MRI) to predict pathological complete response (pCR) and 3-year invasive disease-free survival (3-y iDFS) in HER2+ early breast cancer (EBC) patients (pts): An unplanned exploratory analysis of PHERGain trial

IMPORTANT:

- The document contains the summary of a clinical trial, and its sole purpose is to communicate the results of it to the general public.
- This document is not intended to promote recruitment or provide medical advice.
- The results reflected in this document may contradict those of other trials.
- It is not recommended to make decisions based on the information collected in this document; it should always be consulted with a medical professional beforehand.

ABOUT THIS SUMMARY

SPONSOR:	MEDICA SCIENTIA INNOVATION RESEARCH S.L.
TUMOR TYPE:	HER2-positive early breast cancer
MEDICINE(S) STUDIED:	Trastuzumab, pertuzumab with or without docetaxel and carboplatin
DATES OF STUDY:	2024
TITLE OF THIS STUDY:	Comparing 18F-FDG positron emission tomography (PET) and breast magnetic resonance imaging (MRI) to predict pathological complete response (pCR) and 3-year invasive disease-free survival (3-y iDFS) in HER2+ early breast cancer (EBC) patients (pts): An unplanned exploratory analysis of PHERGain trial
DATE OF THIS REPORT:	May 2024
STUDY FUNDER:	F. Hoffman - La Roche (PHERGain study)
CLINICAL TRIALS.GOV:	NCT03161353 (PHERGain study)

The content for this document was finalised by **Medica Scientia Innovation Research (MEDSIR) - Oncoclínicas&Co** on the 10th of May of 2024. The information in this summary does not include additional information available after this date.

What was the purpose of this study?

The PHERGain phase II trial (NCT03161353) demonstrated the feasibility of successfully treating patients with HER2-positive early breast cancer (EBC) without using chemotherapy, which is the current standard of care. To do so, the researchers used a personalized strategy and evaluated the patient's response to treatment and adapted it (if needed). Treatment response was evaluated (and potentially adapted) at two different time-points: (i) after 2 treatment cycles (evaluating the response with a PET scan) and at surgery (evaluating if the patient had presence or absence of cancer cells). This approach was tested in patients receiving anti-HER2 drugs, trastuzumab and pertuzumab (HP). Due to the limited availability and costs of PET imaging, breast MRI is warranted as an alternative tool for assessing early treatment response after two cycles of HP.

What did researchers want to find out?

The purpose of this subanalysis was to compare PET and MRI results after two cycles of HP in the PHERGain trial to predict the pCR and 3-year invasive disease-free survival (3-y iDFS), which means the proportion of patients who remain cancer-free for three years after surgery, in HER2-positive EBC patients.

When and where did the studies take place?

This is a subanalysis of the PHERGain trial. PHERGain was a multicenter study in 45 hospitals in Europe, from 2017 to 2019

Timeline of the PHERGain study

February 2017
Start of the study- first patient is given study medicine

September 2019
The last patient saw their study doctor for the last time

May 2024

Over 7 countries

Spain, France, Belgium, Germany, UK, Italy, and Portugal.

What were the results of the study?

After two cycles of HP, 79.6% (227/285) of patients from Group B (the strategy group) had a response with PET, 47% (134/285) had a response with MRI (defined as ⩾30% decrease in sum of target lesions), and 82.5% (235/285) achieved an MRI reduction (defined as any decrease in sum of target lesions). A high association was observed between PET response and MRI reduction. Similar rates of pCR and 3-y iDFS were observed between patients with either PET response or MRI reduction. PET-nonresponders without MRI reduction had the worst 3-y iDFS despite receiving standard neoadjuvant treatment with chemotherapy and HP.

What were the main medical conclusions?

The complex design of this study did not allow a direct comparison between PET and MRI.

Although PET is the recommended imaging technique for early treatment response, these data suggest that MRI-assessed tumor shrinkage could alternatively guide pre-surgery treatment after the first two cycles of HP in HER2-positive EBC patients following the PHERGain strategy, when PET is not available.

What were the main social conclusions?

Although PET is the recommended imaging technique for early treatment response, these data suggest that MRI-assessed tumor shrinkage could alternatively guide pre-surgery treatment after the first two cycles of HP in HER2-positive EBC patients following the PHERGain strategy, when PET is not available.

Where I can find more information?

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

For more details, please visit:
https://www.medsir.org/phergain-clinical-trial

The full scientific report of this study is available online at:
www.clinicaltrials.gov

Thank you who took part in the study

If you took part in this study, **Medica Scientia Innovation Research (MEDSIR) - Oncoclínicas&Co**, as the Sponsor, extends its gratitude for your participation. This overview will outline the findings of the study. If you have any queries regarding the study or its outcomes, please reach out to the doctor or staff at your study location.

About Oncoclínicas & CO

Oncoclínicas - the largest cancer care group in Latin America - has a specialized, innovative model that focuses on the entire oncology care process, combining operational efficiency, humanized service and high specialization, through a medical team made up of more than 2,600 professionals, who mainly specialize in oncology. With the mission of making cancer treatment accessible to everyone in the country, it offers a complete operational system made up of outpatient clinics integrated with highly complex oncology centers. It currently has 134 units in 35 Brazilian cities, providing access to cancer care in all regions where it operates, with the quality standards of the best cancer centers in the world.

Through technology, precision medicine and genomics, Oncoclínicas ensures effective results and facilitates access to oncology treatment and has performed more than 595,000 treatments in the last 12 months alone. It is the exclusive partner in Brazil of the Dana-Farber Cancer Institute, an affiliate of Harvard Medical School and one of the most prestigious cancer research and treatment centers in the world. The Group also owns Boston Lighthouse Innovation, a bioinformatics company based in Cambridge, USA, and holds shares in MEDSIR, a Spanish company dedicated to the development and management of clinical trials for independent cancer research. The company is also developing projects in collaboration with the Weizmann Institute of Science in Israel, one of the world's most prestigious multidisciplinary scientific and research institutions, whose international board includes Bruno Ferrari, founder and CEO of Oncoclínicas.

For further information: www.grupooncoclinicas.com

ABOUT MEDSIR

Founded in 2012, MEDSIR works closely with its partners to drive innovation in oncology research. Based in Spain and the United States, the company manages all aspects of clinical trials, from study design to publication, utilizing a global network of experts and integrated technology to streamline the process. The company offers proof-of-concept support and a strategic approach that helps research partners experience the best of both worlds from industry-based clinical research and investigator-driven trials. To promote independent cancer research worldwide, MEDSIR has a strategic alliance with Oncoclínicas, the leading oncology group in Brazil with the greatest research potential in South America. Learn how MEDSIR brings ideas to life: www.medsir.org